

**Response Under 37 CFR 1.116**

**Expedited Procedure**

**Examining Group 1637**

Application No. 10/584,454

Paper Dated: August 27, 2010

In Reply to USPTO Correspondence of May 27, 2010

Attorney Docket No. 4544-101616

**REMARKS**

Claims 1-9 are pending in this application. Claims 2-8 have been allowed and claims 1 and 9 stand rejected. Applicant has added new claims 10-18. Support for these claims can be found in the specification, as originally filed, at, for example, claims 1-9.

Claims 1 and 9 stand rejected under 35 U.S.C. § 103 as obvious over Salotra<sup>1</sup>, Reed<sup>2</sup>, Lowe<sup>3</sup> and Belli<sup>4</sup>.

Claim 1 is directed to a set comprising four primers, SEQ ID NOs: 1-4. Claim 9 is directed to a diagnostic kit for detecting and differentiating VL and PKDL causing strains of *Leishmania donovani*. The kit comprises four primers, SEQ ID NOs: 1-4, among other things.

Salotra teaches using oligonucleotide primers for detecting leishmanial parasites in clinical samples.<sup>5</sup> The oligonucleotide primers are useful to detect *L. donovani* parasites from peripheral blood of visceral leishmaniasis (VL) patients and skin lesions from post kala-azar-dermal leishmaniasis patients.<sup>6</sup> Specifically, Salotra teaches using one set of primers, which differs from each of the sets recited by claims 1 and 9.

Salotra does not teach using two sets of primers, nor does it teach the primers recited in the claims, SEQ ID NOs: 1-4 (see above). Thus, Salotra only teaches one set of primers, which are distinct from those recited in the claim.

Reed discloses a method of diagnosing leishmaniasis by probing a sample with antibodies.<sup>7</sup> As part of its specification, Reed also discloses a 3319 base pair sequence for *Leishmania chagasi*. Reed, however, does not provide a reason to select SEQ ID NOs: 1-4 over any other partial sequence.

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<sup>1</sup> U.S. Publ. Pat. App. No. 2003/0162182 to Salotra *et al.* ("Salotra").

<sup>2</sup> WO 94/16331 to Reed *et al.* ("Reed")

<sup>3</sup> Lowe *et al.*, "A computer program for selection of oligonucleotide primers for polymerase chain reactions," NUCLEIC ACID RESEARCH (1990) 18(7): 1757-1761.

<sup>4</sup> Belli *et al.*, "Simplified polymerase chain reaction detection of new world *Leishmania* in clinical specimens of cutaneous Leishmaniasis," AM. J. TROP. MED. HYG. (1998) 58(1): 102-109.

<sup>5</sup> Salotra at ¶ [0009].

<sup>6</sup> Salotra at ¶ [0010].

<sup>7</sup> Reed at abstract.

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Lowe discloses “a computer program which rapidly scans nucleic acid sequences to select all possible pairs of oligonucleotides suitable for use as primers to direct efficient DNA amplification by the polymerase chain reaction.” The program operates by applying a set of rules to the sequence and target region of the DNA. The rules are designed to enhance primer-to-target sequence hybridization avidity at critical 3'-end extension initiation sites, facilitate attainment of full length extension during the 72°C phase by minimizing generation of incomplete or nonspecific product and limit primer losses occurring from primer-self or primer-primer homologies. However, nothing within Lowe suggests that these rules will provide two sets of primers that will produce unique band separation pattern for VL and PKDL causing strains of *Leishmania donovani*.

When making a rejection under 35 U.S.C. § 103, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness, the prior art must be evaluated based on what it, as a whole, teaches to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971).

As part of a *prima facie* case, an examiner must establish some reason to combine the references. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007); *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007). The *KSR Int'l* Court acknowledged the importance of identifying a reason that would have prompted a person of ordinary skill in the art to combine the elements in the way the claimed invention does. *KSR Int'l*, 127 S.Ct. at 1731; *Takeda Chemical*, 492 F.3d at 1356-1357. Repeatedly throughout the *KSR Int'l* decision, the Court discussed the importance that the result obtained by a particular combination was predictable to one of ordinary skill in the art. *KSR Int'l*, 127 S.Ct. at 1731 and 1739-1742.

In this case, Lowe does not provide a reason for one to select the recited sets of primers. Lowe only suggests that it will generate primer sequences based on a set of rules.

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There is nothing that suggests that the recited primer sets SEQ ID NOs:1 & 3 or SEQ ID NOs: 2 & 4 would have been generated by Lowe's software in the first instances.

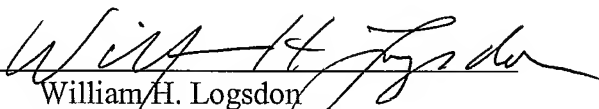
Not only does Lowe fail to provide any suggestions that it will generate even one of the recited primer sets, it also does not provide any suggestion that it will generate two sets of primers that will be compatible with each other, let alone will produce a unique band separation pattern of VL and PKDL causing strains of *L. donovani* as shown in Figure 1 of the specification for the above-captioned application, nor does it provide any motivation to use two sets of primers because Lowe only is directed to applying rules under the assumption that the practitioner will use only one set of primers.

For these reasons, Applicant respectfully requests that the rejection of claims 1 and 9 be reconsidered and withdrawn, and that these claims also be allowed.

Applicant has added new claims 10-18, which are believed to be patentable for the same reasons that claims 1-9 are patentable. Therefore Applicant further request that claims 10-18 also be allowed.

Respectfully submitted,

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